

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

Honorable Thomas Vanaskie
(Ret.),
Special Discovery Master

**THE ZHP PARTIES' REPLY BRIEF IN FURTHER SUPPORT
OF THEIR MOTION TO REDACT AND SEAL PORTIONS OF THE
HEARING TRANSCRIPT OF SEPTEMBER 10, 2021 PURSUANT TO
LOCAL CIVIL RULE 5.3(g)**

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I. INTRODUCTION

Plaintiffs seek to make public portions of the hearing transcript before Special Discovery Master Judge Vanaskie dated September 10, 2021 (the “Sept. 10 Transcript”) in which the parties discussed documents containing information regarding the ZHP Parties¹ confidential, non-public, and proprietary API manufacturing and product process optimization efforts and related testing practices and procedures.² Information regarding the ZHP Parties’ product optimization procedures and testing is highly confidential, competitively sensitive, and would result in certain competitive injury to the ZHP Parties if disclosed to their direct

¹ The ZHP Parties have previously been defined in the ZHP Parties’ motion to seal (the “Motion” or “Mot.”) as Defendants Zhejiang Huahai Pharmaceutical Co., Ltd. (“ZHP”), Prinston Pharmaceutical Inc. (“Prinston”), Huahai U.S. Inc. (“Huahai U.S.”) and Solco Healthcare U.S., LLC (“Solco”). *See* ZHP Parties’ Motion to Redact and Seal Portions of the September 10, 2021 Transcript Pursuant to L. Civ. R. 5.3(g) (the “Motion” or “Mot.”) at 1 (ECF No. [1584-1](#)).

² These documents consisted of (1) an internal email dated July 27, 2017 from a ZHP employee, Jinsheng Lin of ZHP’s technical analysis department (CEMAT), regarding ZHP’s efforts to optimize its production processes for manufacturing irbesartan (the “July 27, 2017 email”); and (2) excerpts of the deposition of Dr. Min Li, another ZHP employee, dated April 20, 2021, in which Dr. Li was asked to disclose his knowledge of the July 27, 2017 email. *See* Mot. at 13 (ECF No. [1584-3](#)). Both the July 27, 2017 email and the relevant portions of Dr. Li’s testimony addressing the July 27, 2017 email were designated “RESTRICTED CONFIDENTIAL INFORMATION” by the ZHP Parties. *See id.* The Court has ordered supplemental briefing on the ZHP Parties’ need to maintain the confidentiality of the July 27, 2017 email and relevant portions of Dr. Li’s testimony, and this brief will be submitted to the Court on November 8, 2021. *See* SMO No. 49 at 9-10 (ECF No. [1667](#)).

competitors. For these reasons, the ZHP Parties have consistently and appropriately designated documents containing this information as “RESTRICTED CONFIDENTIAL” pursuant to the Protective Order, including the documents discussed during the September 10 hearing. Further, the parties specifically requested that the September 10 hearing be conducted *in camera* so that the parties could freely discuss documents disclosing this information, *see* Mot. at ¶ 30, and the Court granted this request.

Plaintiffs’ brief in opposition (“Opposition” or “Opp.”) to the ZHP Parties’ Motion (ECF No. [1652](#)) does not dispute that the ZHP Parties designated these documents as “RESTRICTED CONFIDENTIAL,” or that the Protective Order expressly permits the parties to designate as “PROTECTED INFORMATION” portions of any transcript wherein documents containing “PROTECTED INFORMATION” are discussed. *See* ECF. No. [1661](#), ¶ 17(b). Instead, Plaintiffs challenge the ZHP Parties’ right to seal portions of an otherwise public transcript that would disclose the ZHP Parties’ proprietary information, contradict the plain language of the Protective Order, and mischaracterize the confidential information Plaintiffs seek to publicize. *See* Opp. at 5. Nor have Plaintiffs demonstrated how disclosure of the information at issue could or would inform the public’s understanding of current health and safety issues.

Because Plaintiffs cannot demonstrate that the redacted portions of the Sept. 10 Transcript were improperly designated or that public health and safety interests outweigh the ZHP Parties' interest in preserving the confidentiality of the information disclosed therein, the Court should reject Plaintiffs' challenge and grant the ZHP Parties' Motion to redact and seal the portions of the Sept. 10 Transcript that the ZHP Parties identified in their proposed redactions, which were submitted with the ZHP Parties' Motion.

II. ARGUMENT

A. The Redacted Portions of the Sept. 10 Transcript Were Properly Designated As “RESTRICTED CONFIDENTIAL” Under the Court’s Protective Order

This Court, and courts construing New Jersey law, have repeatedly recognized the need to protect from disclosure confidential research, development, product testing, and other trade secret information involving pharmaceutical manufacturers to protect a litigant’s standing in the marketplace, including API manufacturing process and product optimization procedures. *See In re: Valsartan, Losartan and Irbesartan Prods. Liab. Litig.*, MDL No. 2875, dated May 24, 2021 at 18-19 (the “May 24, 2021 Order”) (granting motion to seal internal notes regarding ZHP’s process optimization strategies where disclosure “would result in significant competitive harm by allowing [competitors] to benefit from ZHP’s proprietary research and development while the FDA restricts ZHP from exporting its products

into the U.S. market.”); *see also Impax Labs., Inc. v. Zydus Pham. (USA) Inc.*, 2:17-cv-13476, 2018 WL 6416910, at *3 (D.N.J. Dec. 6, 2018) (stating, “this Court has protected confidential research and development, product testing, formulations, and other trade secret information, including, but not limited to, the confidential nature of ANDAs, drug master files, formulations, and other confidential testing by drug manufacturers”); *In re Gabapentin Patent Litig.*, 312 F. Supp. 2d at 667 (affirming magistrate judge’s denial of motion to unseal documents that contained information relating to defendant’s ANDA, DMF, processes, formulations, and testing); *Depomed, Inc. v. Purdue Pharma L.P.*, No. 13-571, 2017 U.S. Dist. Lexis 212, at *6-8 (D.N.J. Jan. 3, 2017) (sealing confidential manufacturing and research and development processes and information as well as internal documents, such as laboratory notebooks).

The need to protect competitively sensitive information is essential in the pharmaceutical industry as courts have recognized the need to protect from disclosure competitively sensitive and confidential business information to preserve, and not diminish, a litigant’s standing in the marketplace. *See In re Incretin-Based Therapies Prods. Liability Litig.*, No. 13-md-2452, 2021 WL 873290, *2 (S.D. Cal. Mar. 9, 2021) (granting drug manufacturer’s omnibus motion to seal internal regulatory and safety analyses where “[d]efendants’ interest in safeguarding these

competitive business materials overcomes the general presumption of public access”).³

As emphasized by the declaration of Dr. Min Li, and the ZHP Parties in their proposed findings of fact and conclusions of law accompanying their motion to seal, information regarding the results of the ZHP Parties’ internal process and product optimization procedures with respect to irbesartan is highly confidential, non-public, and competitively sensitive. *See* Mot. at ¶¶ 23-25 (ECF No. [1584-3](#)); *see also* Dr. Li Decl. at ¶¶ 8-10 (ECF No. [1584-5](#)). The ZHP Parties also have described how disclosure of their proprietary API optimization efforts and related testing to their direct competitors would cause the ZHP Parties to suffer significant, non-speculative competitive harm. *See* Mot. at ¶¶ 26-28; Dr. Li Decl. at ¶¶ 8-10. As this Court acknowledged only last week, excerpts from otherwise-public transcripts of hearings in this litigation may be sealed in order to protect a litigant’s commercially sensitive, proprietary information. *See In re: Valsartan, Losartan and Irbesartan Prods. Liab. Litig.*, MDL No. 2875, Order dated October 29, 2021 Granting Motion to Seal

³ Plaintiffs’ attempts to distinguish the authorities on which the ZHP Parties rely is limited to a single footnote, characterizing them as inapplicable because they were “unpublished and unopposed.” *See* Opp. at 13 n.3. But the fact that the motions to seal in those instances were unopposed does not obviate the movant’s burden to demonstrate, *independently*, that its need to maintain the confidentiality of its proprietary information outweighs the public’s interest in accessing judicial records. *See* L. Civ. R. 5.3(c)(3).

Pursuant to L. Civ. R. 5.3(g) at 5, 7 (ECF No. [1691](#)) (granting motion to seal portions of a hearing transcript dated September 13, 2021 filed by Teva Pharmaceutical Industries Ltd., Actavis LLC, and Actavis Pharma, Inc. (collectively, “Teva”), where the excerpts Teva sought to redact “contain commercially sensitive, proprietary information that, if disclosed, would cause Teva clearly defined and serious injury.”).

Plaintiffs argue that the ZHP Parties’ Motion should be denied because the ZHP Parties “do[] not specifically analyze any of its requested redactions in its proposed order or index.”⁴ *See* Opp. at 9. But Plaintiffs’ argument misses the mark for several reasons. First, the Court’s Local Rules do not require movants to submit a line-by-line analysis of each proposed redaction in support of a motion to seal. *See*

⁴ Plaintiffs premise the bulk of their Opposition on mischaracterizations of the contents of the July 27, 2017 email in an effort to exaggerate its importance, as well as baseless speculation as to the ZHP Parties’ motives in seeking to maintain the confidentiality of transcript excerpts that would disclose its contents. *See* Opp. at 1. These attempts have no basis in fact, as demonstrated by the arguments made by ZHP Parties during the September 10 hearing. Instead, they are part of Plaintiffs’ consistent and unsubstantiated efforts to deprive the ZHP Parties of their rights to preserve proprietary information produced in good faith in this litigation pursuant to this Court’s Protective Order in an effort to obtain a tactical advantage over the ZHP Parties and the other manufacturer defendants. Rather than raise confidentiality challenges efficiently, or meet and confer in good faith to redact proprietary information, Plaintiffs have forced the ZHP Parties to file successive sealing motions and oppose an unnecessary motion that alleged, wrongly (as this Court concluded), that the ZHP Parties waived confidentiality as to over eighty documents. These tactics are intended to waste the ZHP Parties’ time and the Courts’ resources, and should be disregarded by the Court.

L.Civ.R. 5.3(c)(3) (requiring “an index … describing with particularity … the nature of the materials or proceedings at issue”). Second, the ZHP Parties have moved to redact and seal portions of the Sept. 10 Transcript, marked as “Protected Information” because they disclose the contents of documents designated by the ZHP Parties as “Restricted Confidential,” specifically the July 2017 email and portions of Dr. Min Li’s testimony. In their Motion, the ZHP Parties explained not only their bases for designating the July 27, 2017 email and Dr. Min Li’s testimony as “Restricted Confidential”—that the documents disclosed proprietary, non-public information—but also provided examples of harm that would befall the ZHP Parties were this information to be disclosed to its competitors. *See* Mot. at ¶¶ 26-28. Finally, together with the Motion, the ZHP Parties furnished line-by-line proposed redactions to indicate which portions of the Sept. 10 Transcript should be sealed. This was done to minimize the ZHP Parties’ redactions, and to avoid any unnecessary redactions. Simply, there is no basis for Plaintiffs’ claim that the Motion lacks specificity.

Likewise, Plaintiffs’ assertion that the Motion divulges facts the ZHP Parties ask the Court to redact from the Sept. 10 Transcript (Opp. at 10) is belied by the very examples they identify: these are not limited to general statements about the ZHP Parties’ product optimization process, but describe, respectively, the contents of a

ZHP employee's contemporaneous handwritten lab notebooks (10:17), and the contents of the July 27, 2017 email (18:2-3 and 19:7-9). *See* Opp. at 10.

Nor is there any basis to Plaintiffs' claim that the Motion must be dismissed because the ZHP Parties have not moved to seal Exhibits A and B to the Sept. 10 Transcript. Exhibits A and B are PowerPoint slides prepared by the ZHP Parties' counsel, which were presented during the September 10 hearing as demonstratives to the ZHP Parties' arguments for the Court's edification. These exhibits were not affixed to the Sept. 10 Transcript, provided to the court reporter, or otherwise made publicly available. *See* Opp. at 10.

Moreover, the ZHP Parties do not dispute that the patent attached to the July 27, 2017 email is publicly available, nor have they sought to seal information specifically attributable to the patent. But Mr. Lin's analysis of the patent, which he communicated to ZHP employees within the scope of his employment, is most assuredly not public, nor was it ever intended to be.

Finally, Plaintiffs attempt to mischaracterize the declaration of Dr. Min Li as inconsistent with his sworn deposition testimony. *See* Opp. at 1. But there is no inconsistency between Dr. Li's deposition testimony and his subsequent declaration. As Plaintiffs concede, during his deposition Dr. Li testified clearly and honestly that he did not recall receiving the July 27, 2017 email. *See id.* at 1-2. Conversely, Dr. Li's declaration focused on his review of the July 27, 2017 email and contains his

opinion that any public disclosure of the July 27, 2017 email and related information would place the ZHP Parties at a competitive disadvantage given its technical, proprietary, confidential, and non-publicly disseminated content, which would be of significant competitive value to the ZHP Parties' competitors. *See* Dr. Li Decl. at ¶¶ 9-10 (ECF No. [1584-5](#)).⁵

B. Plaintiffs Do Not Articulate How the Redacted Portions of the Sept. 10 Transcript Relate To, Let Alone Inform, Public Health and Safety Concerns

Plaintiffs premise their Opposition on the broad assertion that the Court "should recognize the significant public interest in understanding the nitrosamine [impurity] at issue in this case" and, in particular, the ZHP Parties' knowledge of alleged nitrosamine impurities predating the recall of the ZHP Parties' valsartan products.⁶ *See* Opp. at 4, 11. Plaintiffs also allege, without basis, that by moving to

⁵ Plaintiffs further attempt to characterize the July 27, 2017 email as "a document the contents of which ZHP has already waived confidentiality." *See* Opp. at 4 n.1. This Court has flatly rejected Plaintiffs' argument. *See* SMO No. 49 at 10 (ECF No. [1667](#)).

⁶ As the Court has acknowledged, Plaintiffs have advanced this argument repeatedly in seeking to publicize the ZHP Parties' proprietary, non-public information, and has advised Plaintiffs to assert their objections with greater specificity. *See* Case Management Conference Tr. dated Oct. 27, 2021 at 22:2-9 ("I'm hoping, from the Plaintiffs' perspective, or speaking to you as the Plaintiffs' counsel, and speaking to all Plaintiffs' counsel, that you just don't rely upon the assertion about—and this is, it's a very important matter and it does involve public health and safety, I understand that; but I hope there's a little more meaningful discussion or much more meaningful discussion than simply making that assertion").

redact and seal portions of the Sept. 10 Transcript, as is their right under Paragraph 17(b) of the Protective Order, the ZHP Parties seek to “hide the information needed for a true understanding of the nitrosamine contamination of its pharmaceuticals.” *See* Opp. at 13. However, Plaintiffs omit the fact that ZHP Parties themselves produced the July 27, 2017 email in the normal course of discovery.

Notwithstanding Plaintiffs’ advocacy, Plaintiffs neglect to identify a single case in support of their position that a movant’s interest in maintaining the confidentiality of its proprietary process optimization procedures is outweighed by such generalized, unspecified health and safety concerns. Plaintiffs make no attempt to engage with any of the factors identified by the Third Circuit in its *Avandia* decision, in which the Court held that multiple discretionary factors should be considered as part of a balancing test in determining whether a movant’s interest in preserving confidential information outweighs the public’s right to access judicial records. *See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 671 (3d. Cir. 2019). Plaintiffs do not allege, for example, nor could they, that the redacted portions of the Sept. 10 Transcript reveal information regarding the ZHP Parties’ manufacturing and testing processes for valsartan API intended for distribution in the United States. Nor do Plaintiffs allege that the redacted portions of the Sept. 10 Transcript either summarizes, contextualizes, or analyzes any alleged manufacturing or testing processes or concerns that resulted in the NDMA impurity

in valsartan. Thus, the “public concern” central to Plaintiffs’ Opposition is absent in the context of the Sept. 10 Transcript and document sought to be sealed.⁷

III. CONCLUSION

For the foregoing reasons, and those asserted in its Motion, the ZHP Parties respectfully request that the Court grant the ZHP Parties’ Motion to Redact and Portions of the Sept. 10 Transcript Pursuant to Local Civil Rule 5.3(g).

Dated: November 1, 2021

Respectfully submitted,

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⁷ Conversely, as outlined in the Motion, several of the *Avandia* factors weigh against disclosure of the redacted portions of the Sept. 10 Transcript, including the non-public and proprietary nature of the process optimization and testing information at issue; the intent of the July 27, 2017 email’s author, Jinsheng Lin, not to disseminate the information beyond the ZHP Parties; and the non-speculative risk of competitive harm to the ZHP Parties as a result of disclosure. *See* Mot. at ¶ 34.

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CERTIFICATE OF SERVICE

I, Kelly A. Bonner Esq., hereby certify that a complete copy of the foregoing ZHP Parties' Reply Brief in Support of Their Motion to Redact and Seal Portions of the September 10 Transcript Pursuant to Local Civil Rule 5.3(g) has been filed electronically on the docket in this matter, and is available for viewing and downloading from the ECF system. This document is being served upon the following counsel on November 1, 2021 through the ECF system, and a courtesy copy is being sent by email:

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